

5508

100 OCT 22 10 51

5467 Panoramic Lane
San Diego, CA 92121

Sept. 22, 2000

Commissioner Jane Henney

re: Docket No. 00P-1211 \ CP1

and re: Any other docket no. regarding
genetically engineered products
or organisms

FDA Dockets Management Branch
(HFA-305)

5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Doctor Jane Henney,

I am writing to you to express my
grave concern over FDA's ^{regulation} regulation + lack of
of genetically engineered food, food additives,
drugs and any other genetically engineered
substance or organism. I request that the
agency's ^{actions and} policies be changed immediately.

From what I have read, been told, and
seen, I believe that lives are on the line.

C6413

② You must declare an immediate recall
and ban on sale or distribution (for free
or for fee or sale or barter) of all genetically
engineered products - including, but not
limited to - food, fragrances, fiber, wood,
toiletries (including tampons), food additives,
cosmetics, drinks, paper, inks, furniture, soaps,

00P 1211

detergents,
 clothes, toys, seeds, plants (both seed & plants are often grown for food), vitamins, supplements. You must not allow these things to be sold or given to people or other entities in the U.S.A. nor elsewhere in the world.

I and others know someone who died after genetically engineered (GE) food, food additives, & fragrances were produced and released. The person who died - died a gruesome death as a result of vasculitis. As you must know, allergies can cause vasculitis. This person's doctor and others noted that this person was much better when they didn't eat & were not around fragrances. Months before this person died, neither doctors nor this person expected this person to die. If you look at Dr. Metcalf's book entitled Food Allergies (2 1977) you will see many horrible symptoms this person suffered from as this person died.

I and others also know someone else who has suffered from and continues to suffer from many of the same symptoms as the first person described above. These symptoms occur in ~~for~~ person number 2 when eating, after eating (or sometimes when in the same room with food items or fragrances or drugs.

or plants. This person used to enjoy eating most anything. Now this person's diet is severely limited. This person's allergic symptoms blew up and almost killed this person after the release of genetically engineered food, food additives, and fragrances. This person has been tested ^{& found} to have true food allergies to almost all of the foods on the list of GE "Foods on Market" at the website of ucsuusa.org

The experiences of person no. 1 and person no. 2 may be a coincidence, or they may not be. From what I have seen and read & been told by scientists, I believe these are not coincidences.

I and others know a third person who gets sick ^{now} when they open the newspaper. They did not ~~used to~~ ^{in the past} get sick from the newspaper. As you must know, over half of soy in the U.S.A. is genetically engineered. And as you probably know, soy inks are in extensive use now. The symptoms this person experiences look like allergic symptoms. A coincidence? Maybe, maybe not.

People who make genetically engineered food tell me that over 600 foods have been engineered in labs. It appears that there are plans ^{to} genetically engineer all food. If so, ~~this~~ ^{the} second person and others, ^{appears,} it will be able to eat nothing or they will die a gruesome death.

Dr. Henney, act now to protect human lives. I believe that lives are on the line.

I have told much of the above to numerous politicians. It appears to me that ^{many} politicians of both major parties care more about money (to get elected - from the industry ^{is} that makes and develops, and sell GE products) than they care about human lives. I wonder - no - it seems to me that they value power more than they value ~~preventing~~ preventing gruesome human deaths.

As I understand it,
 When Dr. Metcalf proposed a "decision tree" for releasing & marketing GE foods, he acknowledged ~~that possibility~~ that there are people who "would not" be protected by that "decision tree".
 Someone told me that it is 10% ^{GE}.
 So, are the politicians, the ^{GE} industry, and even you - a Doctor - saying and going to

say "to hell with those people who are the 10%"? Because if these 10% of the people are forced to eat GE food ^{I believe} (because it is not labeled, ^{as I understand,} because it ~~does~~ has been shown ^{to} cross pollenate with food in non GE fields, because it appears that all food will soon be GE - unless you or someone stops its production ^{and} release) their lives and deaths will be hell.

I think the people, ^{I believe} who inflict this this suffering on others, should spend a month watching the death of someone they have (I believe) put this cruel sentence on. They might see a human person having bloody ~~diarrhea~~ diarrhea after eating and eventual kidney failure, they might see the suffering person's blood vessels red and broken down by inflammation - those blood ~~vessels~~ vessels bleeding in one organ and then another - including the brain. They might see the person's body inflated beyond recognition - inflated grotesquely by edema. And they might see pleading eyes and hands and tears.

I and others have seen these things. We have seen suffering we never could have imagined.

I have read research that food allergies have increased since GE food has been released. There is a theory that if a person is exposed to a virus at the same time that they eat a food, they become allergic to the food. You must know that the cauliflower mosaic virus, ^{or other virus} has been inserted into most GE food and drugs and textile plants - this is my understanding from reading and talking with scientists. So GE foods, drugs, & textiles ^{inks, etc.} may be causing new allergies to foods, drugs, & textiles ^{and inks} (re textiles, I understand that our skin can absorb what is on it).

Further, I have read that there is research linking cauliflower mosaic virus with cancer. And I have read that some GE foods on the market are linked with cancer (eg. ^{GE} dairy products and breast cancer ^{have been} linked).

There is more that I and others know and or have seen regarding the appearance of a link between genetically engineered products and severe illness.

I request that you meet with me in person in my home and I will tell you more. I do not wish to be exposed more than I have to, to the fragrances (likely, I understand, to be GE) and cleaners

(often, I understand containing GE products) that appear to be present in most hotels. You must know that about 90% of fragrances are GE (I read that somewhere).

Doctor Henney I hope you remember the health and human lives that have been entrusted to you as a Doctor and by virtue of your position as Commissioner of the FDA. I believe that lives are on the line.

① Please meet with me in person. I will give you a cordial welcome.

~~①~~
 ② Recall all GE products now as in the description of ② at the beginning of my letter. Make this recall public with a full televised press conference and a full written transcript and further details for all Americans and all doctors to be able to see and hear and read. Further, ^{make} translations ^{for all countries affected or likely to be exposed} and ^{are or} release them for all countries which ^{are or} may be consuming GE products (our country ^{its government & industry,} makes most GE products and must take responsibility for its actions). Tell the people of all countries and their doctors what symptoms they may be suffering from or seeing in others as a result of ^{exposure to} genetically engineered products. Tell people how they might safely dispose of GE products (by

incineration?) since I've been told ^{by scientists} that the virus inserted may persist in future plants, animals, & peoples' bodies and their offspring's bodies (if pregnant when eating GE food, for example). Let people know that there is scientific evidence that genetically engineered organisms and products with them or made with them, may be making them ill or even killing them.

③ Require long term studies by independent researchers with informed willing ^{human} volunteers for at least 7 human generations. ~~before~~ This research must show that there are no ill effects to people in order to allow the sale or giving or distribution or release or barter of GE organisms.

Scientists tell me that GE plants are tested for 7 generations and there are still unexpected results. This technology is, in my and many other scientists' opinion, too new ^{too dangerous, and too} ~~and~~ unpredictable to be released.

④ Any experimental ^{or other} GE organisms must be destroyed (incinerated?) as well as any byproducts of the making of GE organisms. (As I understand that the industry is or wishes to recycle GE wastes. ~~to~~ I believe this ^{recycling} practice must not be allowed). This holds true (require destruction) for organisms made with GE organisms.

⑤ I have read that often times the same companies that make and sell & develop GE products (that may be giving people cancer, digestive problems, allergic reactions, gruesome deaths) also own the drug companies (that make money when people with the above mentioned diseases need to buy their medicines or pay tax dollar for research into cures.) It appears to me and others that this type of dual ownership could create a conflict of interest or worse. I can not tell you anyone else's intent, but I and others believe that this type of monopoly ~~should not~~ must not be allowed to exist. Change the regulations so that a company can not make and sell both food and medicine. Allow them to sell neither food nor ~~drugs~~ if they own any form of media (eg newspaper, TV stations, etc.)

⑥ If you allow experimentation with GE organisms, ^{or their production} you must ~~see~~ see to it & require-frequent (at least **5** times a year) on site, unannounced inspections of all places with GE organisms - to make sure regulations are being followed.

⑦ IF ^{GE} food or other GE products (or products made with GE organisms) are released for public ^{exposure} (which I and many other scientists believe to be unwise.) - they must be clearly labeled with all ~~specific~~ ingredients listed with their specific names. There must

no longer be secret ingredients in GE products nor in any other product (as any ingredient can cause severe allergic reaction or death in some people - scientists have told me).

All GE products must ^{be} clearly state ~~or~~ labeled "Genetically Engineered ^{and} made with Genetically Engineered ingredients - as the case may be) containing (and/or "made with" - as the case may be) ~~of~~ ... (listing all ingredients inserted - vectors, markers, genetic material from specific species, metals, bacteria bits or whole, virus parts or whole, fungus parts or whole, or any other added thing - all specific names must be given).

⑧ Makers of GE ^{organisms or} products and sellers and distributors, ~~of~~ and experimenters must be made liable for damages to human beings and to the environment with no time limit since genetic damage ~~some~~ and other damage sometimes takes years or even generations to show up. ^{liability} This ^{liability} must apply to individuals, companies, governments and any other entity making, selling, distributing, and or experimenting with GE organisms or products.

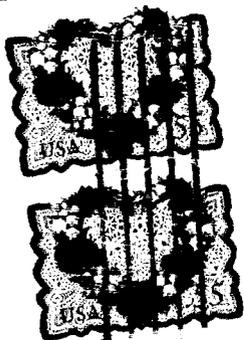
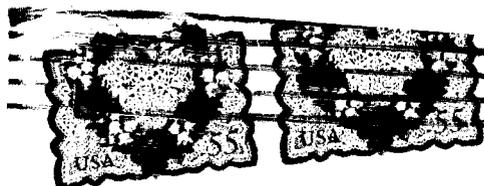
Doctor Henney, thank you for taking
the time to read this.

Please take ^{these} immediate actions.
I and many others believe that the
evidence indicates that lives are on
the line.

Best Regards,

Pat
Pat Holland
Advocate
Phone (858) 455-1033

5467 Panoramic Lane
San Diego, CA 92121



Commissioner Jane Henney
Docket No. 00P-1211 \ CP 1
FDA Dockets Management Branch
(HFA* - 305)
5630 Fishers Lane, Room 1061
Rockville MD 20852
